

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stephen T. Sonis and Edward G. Fey

Serial No: 09/800,855

Art Unit: 1614

Filed: March 7, 2001

Examiner: C. Delacroix-Muirheid

For: ***METHODS AND COMPOSITIONS FOR TREATING AND PREVENTING  
MUCOSITIS***

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

**TERMINAL DISCLAIMER TO OBLVIAE A PROVISIONAL DOUBLE  
PATENTING REJECTION OVER AN ISSUED PATENT**

Sir:

Petitioner, Mucosal Therapeutics, LLC, is the owner of the entire interest in the above-identified application and U.S. Patent No. 6,458,777, issued October 1, 2002, as evidenced by the accompanying Certificates under 37 C.F.R. § 3.73(b). Petitioner hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. §§ 154-156 and 173 as shortened by any terminal disclaimer filed prior to the grant of U.S. Patent No. 6,458,777, issued on October 1, 2002. Petitioner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and U.S. Patent No. 6,458,777 are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. §§ 154-156 and 173 of U.S. Patent No. 6,458,777 as

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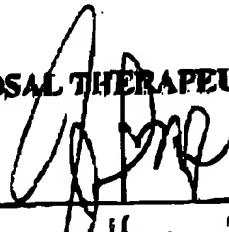
U.S.N. 07/801,855  
Filed: March 7, 2001  
TERMINAL DISCLAIMER TO DEVIATE A  
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OVER AN ISSUED U.S. PATENT

shortened by any terminal disclaimer filed prior to the patent grant. In the event that U.S. Patent No. 6,458,777, expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 C.F.R. § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term, is shortened by any terminal disclaimer filed prior to its grant.

The undersigned (whose title is supplied below) is empowered to act on behalf of Mucosal Therapeutics, LLC.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

MUCOSAL THERAPEUTICS, LLC

By:   
Name: Harry Barnett  
Title: Manager

Date: November 13, 2002  
ATL 104881-1

PTO/SB/08 (08-02)  
Approved for use through 09/30/2002. GMB 0621-0251  
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**STATEMENT UNDER 37 CFR 3.73(b)**

Applicant/Patent Owner: Stephen T. Sonis and Edward G. Foy  
Application No./Patent No.: 09/800,855 Filed/Issue Date: March 7, 2001  
Entitled: Methods and Compositions for Treating and Preventing Mucositis  
Assignee: Mucosal Therapeutics, LLC, a Limited Liability Corporation  
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

States that it is:

1.  the assignee of the entire right, title, and interest; or  
2.  an assignee of less than the entire right, title and interest.  
The extent (by, percentage) of its ownership interest is \_\_\_\_\_ %

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A.  An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 010209 Frame 0999, or for which a copy thereof is attached.

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[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.06]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

November 13, 2002  
Date

Henry R. Rutherford  
Typed or printed name  
Henry R. Rutherford  
Signature  
Manager  
Title

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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Stephen T. Sonis and Edward G. Fey  
 Application No./Patent No.: 6,458,777 Filed/Issue Date: October 1, 2002  
 Entitled: Methods and Compositions for Treating and Preventing Mucositis  
Mucosal Therapeutics, LLC, a Limited Liability Corporation.  
 (Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

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The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

November 13, 2002  
Date

Harry Fey  
Typed or printed name  
Manager  
Signature  
Title

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